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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/642,218	08/18/2000	Olga Yurieva	600-1-179N CON	6461

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EXAMINER	
HUTSON, RICHARD G	

ART UNIT	PAPER NUMBER
1652	4

DATE MAILED: 01/24/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Offic Action Summary	Application No. 09/642,218	Applicant(s) YURIEVA ET AL.	
	Examiner Richard G Hutson	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-73* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-73* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-6, 73, drawn to a DNA Polymerase III-type enzyme from a thermophilic bacterium, classified in class 435, subclass 194.

II. Claims 7-10, 11-15, 22-26, 27-37, 38-42, 52-60, 61-63, 44-51, 64, 68-72, drawn to a nucleic acid encoding at least a single subunit of a DNA polymerase III-type enzyme from a thermophilic bacterium, classified in class 435, subclass 194.

III. Claims 16-21, drawn to a subunit of a DNA polymerase III-type enzyme, classified in class 435, subclass 194.

IV. Claim 43 and 65, drawn to a method for isolating a target DNA fragment that encodes a thermostable DNA polymerase III-type enzyme or subunit thereof, classified in Class 435, subclass 6.

V. Claim 66, drawn to a method for amplifying a nucleic acid molecule, classified in Class 435, subclass 91.1.

VI. Claim 67, drawn to a DNA molecule amplified by the method of claim 66, classified in Class 536, subclass 23.1.

For each of inventions II, III and V above, restriction to one of the following is also required under 35 USC 121:

(A). SEQ ID NO: 3 or a sequence encoding SEQ ID NOs: 4 and 5 (γ subunit)

(B). SEQ ID NO: 3 or a sequence encoding SEQ ID NO: 2 (τ subunit)

(C). SEQ ID NO: 94 or a sequence encoding SEQ ID NO: 95 (ε subunit)

(D). SEQ ID NO: 86 or a sequence encoding SEQ ID NO: 87. (α subunit)

(E). SEQ ID NO: 106 or a sequence encoding SEQ ID NO: 107. (β subunit)

For invention IV, above, restriction to one of the following is also required under 35 USC 121;

(F). SEQ ID NO: 6

(G). SEQ ID NO: 8

(H. SEQ ID NO: 10

(I). SEQ ID NO: 11

(J). SEQ ID NO: 12

(K). SEQ ID NO: 13

(L). SEQ ID NO: 14

(M). SEQ ID NO: 15

(N). SEQ ID NO: 16

Therefore, an election of one of inventions II-V also requires an election of one of inventions (A)-(N).

Claims 11, 44, 61 and 68-72 link(s) inventions (A) through (E). The restriction requirement between the linked inventions is subject to the nonallowance of the linking claim(s), claims 11, 44, 61 and 68-72.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions (A)-(E) and (F)-(N) are chemically and structurally unrelated. In the instant case the different inventions, represent chemically and structurally different polypeptides and the polynucleotides encoding them. Therefore, where structural identity is required, such as for hybridization or expression, the different sequences have different effects and require different searches.

Inventions I and III are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the DNA Polymerase III-type enzyme claimed does not require the claimed DNA Polymerase III subunits. The subcombination has separate utility such as the use of the DNA Polymerase III subunits for the synthesis of antibodies against the subunits for their use in a diagnostic assay .

Inventions II and inventions I, III and VI are structurally unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to divergent molecules having different functions and effects. In the instant case the DNA polymerase III-type enzyme of Group I, the DNA polymerase III-type enzyme subunit of group III, the undisclosed DNA molecule of Group VI and the polynucleotides of Group II each comprise a chemically unrelated structure capable of separate manufacture, use and effect. The polypeptides of Groups I and III are comprised of different amino acid sequences and the polynucleotides of Groups II and VI are comprised of different nucleic acid sequence. The polynucleotides of Group I can be used in hybridization assays as well as in expression methods for producing polypeptides. The DNA

polymerase III-type enzyme of group I and the DNA polymerase III-type enzyme subunits of group III may each be used in nucleic acid synthesis methods as well as in methods of generating antibodies.

Inventions II and invention IV are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the polynucleotide can be used in a materially different process such as one in which the polynucleotide is used to transform a bacterial host cell for heterologous expression of the polypeptide.

The polypeptides of Groups I and III and the DNA of Group VI are unrelated to the method of Group IV as they are neither used nor made by the method of Group IV.

Inventions I and invention V are related as product and processes of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the DNA polymerase III-type enzyme can be used can be used in a materially different process such as one in which the enzyme is used to introduce mutations into a polynucleotide sequence.

Inventions V and VI are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the DNA of Group VI can be made synthetically or naturally by the organism in which it naturally occurs.

The polynucleotide of Group II, the polypeptide of Group III are unrelated to the method of Group V as they are neither used nor made by the method of Group V.

The methods of Groups IV and V are independent as they comprise different steps, utilize different products and produce different results.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and the literature and sequence searches required for each of the Groups are not required for another of the Groups, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

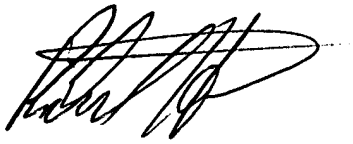
Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (703) 308-0066. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (703) 308-3804. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



Richard Hutson, Ph.D.
Patent Examiner
Art Unit 1652
January 10, 2003